

REMARKS

1. The application was filed with Claims 1-44, of which Claims 31-44 have been withdrawn pursuant to a restriction. Claim 12 was cancelled and new Claim 45 added in the amendment filed on March 21, 2007. Claims 1-11, 13-30 and 45 are pending in the application. Claims 1, 3, 8, 11, 14-24, and 26 are rejected under 35 U.S.C. § 103(a) as unpatentable in view of U.S. Pat. No. 6,190,371 to Paul Maginot et al. ("Maginot") and further in view of U.S. Pat. No. 5,735,831 to Kirk Johnson et al. ("Johnson"). Claims 1, 2, 4, 5, 7, 9-10, 13, 23, 29, and 30 are rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Pat. No. 5,106,376 to Pekka Mononen et al. ("Mononen") in view of U.S. Pat. No. 5,735,831 to Kirk Johnson et al. ("Johnson"). Claims 1, 6, 16, 25, 27, 28 and 45 are rejected under 35 U.S.C. § 103(a) as unpatentable in view of U.S. Pat. No. 5,782,797 to Cyril Schweich, Jr. et al. ("Schweich") in view of U.S. Pat. No. 5,735,831 to Kirk Johnson et al. ("Johnson").

2. Claims 1, 3, 8, 11, 14-24, and 26 are rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Pat. No. 6,190,371 to Paul Maginot et al. ("Maginot") in view of U.S. Pat. No. 5,735,831 to Kirk Johnson et al. ("Johnson"). The rejection admits that Maginot does not teach or suggest the plurality of side apertures on the extraperitoneal end of the catheter. Office Action, p. 2, lines 17-18. The rejection then states that Johnson, Fig. 1, teaches apertures on the proximal end of an insert located inside a catheter, and that it would have been obvious to modify the catheter of Maginot with an insert having a plurality of apertures as taught by Johnson "since such a modification would allow for even more fluid distribution within the catheter." Office Action, p. 2, lines 19-22.

Applicants traverse the rejection. Applicants have invented a dialysis catheter. The new catheter is intended to avert problems associated with the prior art, including leakage problems, as stated in the application as filed, and specifically in paragraphs [0008] and [0009]. The leakage is averted, and operation of the catheter is controlled, by an obstructor or insert inside the catheter. See application paragraphs [0015] and [0018]. Accordingly, the dialysis catheter has two pluralities of apertures, as recited in independent Claims 1 and 16 (or a single plurality as recited in Claim 23), and an insert, also known as an obstructor, that fills a majority of the interior space defined by the catheter. The rejection cites Maginot as teaching a catheter 34 and an insert 2.

Applicants are unable to find any "insert (2)" in Maginot and assume that the Office Action refers to working catheter 42, as depicted in Maginot Figs. 3 and 7A. If this is not

correct, then Maginot does not teach or disclose “insert (2)” and fails to teach or suggest the recited insert. Catheter 42 of Maginot has only two proximal orifices 48, 52 and two distal orifices, 50, 54. See Maginot, col. 8, lines 41-51, and Figs. 3, 5, and 7A. The purpose of having only two distal orifices, and no side orifices, is to position the distal orifices 50, 54 near the superior vena cava for hemodialysis. See col. 11, lines 48-52. Hemodialysis “is then performed on the patient’s body in a well known manner,” col. 11, lines 64-65, i.e., one orifice and lumen is used to withdraw blood from the vena cava and forward it to a dialyzer, and the other lumen and orifice are used to return the dialyzed blood to the vena cava. This makes it clear that the purpose of having only two proximal orifices is to connect catheter 12 to a dialyzer, i.e., blood-in and blood-out connectors. Maginot teaches no side orifices because no side orifices are needed or desired in hemodialysis; Maginot teaches only end orifices.

Since Maginot lacks side orifices, the Office Action then cites Johnson, Fig. 1, as teaching side orifices in an “expandable flowrate” catheter. Office Action, p. 2, lines 18-19. The rejection then states that modifying the catheter of Maginot with the side apertures of Johnson would “allow for even more fluid distribution within the catheter.” Office Action, p. 2, lines 19-22. Applicants agree that adding side apertures to Maginot would indeed allow for more fluid distribution within the catheter i.e., it would cause blood being withdrawn to mix with blood being returned. Thus, blood drawn from the vena cava that has not been dialyzed and is in need of dialysis would be mixed with blood being returned from the dialyzer that does NOT need further dialysis. The dialyzing procedure would be less efficient and would take longer for the patient. Shortening dialysis time and preventing this mixing is why Maginot has two separated distal orifices 50, 54. See col. 12, lines 23-34. Additional side orifices also increase the likelihood of leakage and would frustrate the purpose of Maginot’s two valves 37, 39. See col. 13, lines 45-49.

Accordingly, adding Johnson’s side orifices would frustrate Maginot’s invention and would make Maginot’s hemodialysis catheter unsuitable for its intended purpose: rapid, leak-free hemodialysis. Accordingly, the prior art does not suggest the desirability of the combination, per M.P.E.P. 2143.01 (I), and the proposed modification renders the prior art unsatisfactory for its intended purpose, per M.P.E.P. 2143.01 (V). Both of these violate the basic requirements of a *prima facie* case of obviousness. M.P.E.P. 2143. Thus, the Office Action fails to make out a *prima facie* case of obviousness, and Claims 1, 3, 8, 11, 14-24 and 26 are allowable. In addition, other claims depending from independent Claims 1, 16 and 23 are also allowable, including Claims 2, 4-7, 9-10, 13, 25-30, and 45.

In addition, the rejection does not cite limitations or references teaching or suggesting the limitations for many of the dependent claims rejected under Maginot and Johnson. For example, the Office Action does not cite any reference for the trocar of Claim 18, or the bead and flange of Claim 21. For these additional reasons, at least Claims 18 and 21 are further allowable over the cited art.

3. Claims 1, 2, 4, 5, 7, 9-10, 13, 23, 29, and 30 are rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Pat. No. 5,106,376 to Pekka Mononen et al. ("Mononen") in view of U.S. Pat. No. 5,735,831 to Kirk Johnson et al. ("Johnson"). Mononen discloses an epidural anesthesia catheter set 10, in which cannula tube 11, spinal cannula 20, and thin cannula tube 21 each have only a single distal opening. The reason for the single opening is clear, when viewing Figs. 2, 3, and 4, that is, accurate delivery of spinal anesthesia. This is also discussed in the specification, col. 4, lines 47-52, which states that the catheter delivers anesthesia to the patient's spinal space.

The rejection admits that Mononen does not teach or suggest side apertures, and cites Johnson as teach a plurality of side apertures. The rationale for the combination is that adding side apertures would allow for even more fluid distribution within the catheter. See Office Action, p. 3, lines 7-10. By reasoning similar to that for the rejection of claims over Maginot and Johnson, the use of side apertures is not suggested by Mononen and is clearly not appropriate for Mononen. Additional side apertures in Mononen's catheters 11 and 20 would add nothing, since these catheters are not in actual contact with the anesthetic. Adding apertures to catheter 21 would result in leakage of the anesthesia out of the catheter. This would result in placing anesthesia in inappropriate places, and might have the practical effect of failing to deliver sufficient anesthesia to the desired location, the patient's spinal space.

Accordingly, the prior art does not suggest the desirability of the combination, per M.P.E.P. 2143.01 (I), and the proposed modification renders the prior art unsatisfactory for its intended purpose, per M.P.E.P. 2143.01 (V). Both of these violate the basic requirements of a *prima facie* case of obviousness over Mononen and Johnson. M.P.E.P. 2143. Thus, the Office Action fails to make out a *prima facie* case of obviousness, and Claims 1, 2, 4, 5, 7, 9-10, 13, 23, 29, and 30 are allowable. In addition, other claims depending from independent Claims 1 and 23 are also allowable, including Claims 3, 6, 8, 14-15, and 24-28.

In addition, the rejection does not cite limitations or references teaching or suggesting the limitations for many of the dependent claims rejected under Mononen and Johnson. For example, the Office Action does not cite any reference for the coiled end or perpendicular disc of Claim 4, that a plurality of apertures constitute grooves, as recited in Claim 10, or the elongated flute of Claim 13. For these additional reasons, at least dependent Claims 4, 10 and 13 are further allowable over the cited art.

4. Claims 1, 6, 16, 25, 27, 28, and 45 are rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Pat. No. 5,782,797 to Cyril Schweich, Jr. et al. ("Schweich") in view of U.S. Pat. No. 5,735,831 to Kirk Johnson et al. ("Johnson"). Schweich discloses a therapeutic infusion device with a first series of apertures for delivering a neuroprotective drug to a location distal to a thrombic occlusion and a second series of apertures for delivering a thrombolytic agent to a location proximal to the occlusion. See Abstract. The Office Action admits that Schweich does not teach a plurality of side apertures on an extraperitoneal end of the device, but argues that Johnson does so teach, and that adding Johnson's extraperitoneal apertures "would allow for more even fluid distribution within the catheter." Office Action, p. 3, last four lines.

As far as Applicants can discern, adding extraperitoneal apertures that allow for more even fluid distribution within the catheter would allow the two drugs to mix with each other, or would allow the drugs to leave the catheter at a location other than the present two series of apertures. Either way, modifying Schweich with Johnson's additional extraperitoneal apertures would clearly frustrate Schweich's intention to deliver only one first drug to a desired first location and a different second drug to a desired and different second location.

By the same reasoning used above in the other rejections, the prior art thus does not suggest the desirability of the combination of Schweich and Johnson, per M.P.E.P. 2143.01 (I), and the proposed modification renders the prior art unsatisfactory for its intended purpose, per M.P.E.P. 2143.01 (V). Both of these violate the basic requirements of a *prima facie* case of obviousness. M.P.E.P. 2143. Thus, the Office Action fails to make out a *prima facie* case of obviousness, and Claims 1, 6, 16, 25, 27, 28, and 45 are allowable. In addition, other claims depending from independent Claims 1 and 16 are also allowable, including Claims 2-5, 7-11, 13-15, and 17-22.

In addition, many of the limitations of the dependent claims are not cited in the Office Action. For example, there is no mention of the perpendicular discs or the coiled intraperitoneal end recited in Claim 28, or the grooves recited in Claim 45. For this reason, at least Claims 28 and 45 are additionally allowable.

5. Applicants assert that the claims are allowable and respectfully request the Examiner to reconsider the rejections and to allow the claims of the application. The Commissioner is hereby authorized to charge deposit account 02-1818 for any fees which are due and owing.

Respectfully submitted,

BELL, BOYD & LLOYD LLP

BY


David W. Okey

Regis. No. 42,959

Customer No. 29200

Dated: July 11, 2007